WRITTEN TESTIMONY

OF

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BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATINON

COMMITTEE ON ENERGY AND COMMERCE

ON

AWP-BASED REIMBURSEMENT FOR PRESCRIPTION DRUGS BY MEDICAID

December 7, 2004

Witness Statement
For
Oversight and Investigations Subcommittee Hearing
On
December 7, 2004

Mister Chairman, Members of Congress,

My name is Edward Stratemeier. Until recently I was Senior Vice President of Aventis Pharmaceuticals. My responsibilities included legal matters, government relations and public policy in North America. Aventis is a global pharmaceutical company that has just been acquired by Sanofi-Synthelabo to form Sanofi-Aventis. As a result of the merger I left the company.

I am here today at the Committee's request as a private citizen. I understand that the purpose of today's hearing is to address issues relating to AWP-based reimbursement of prescription drugs under Medicaid. I have been asked to discuss with the Committee the policy position developed by Aventis during my tenure there with respect to AWP based reimbursement for prescription drugs.

I joined Marion Laboratories, one of the predecessor companies of Aventis in 1982. Over the past twenty years I have been actively engaged in the prescription pharmaceutical industry as an attorney and a senior executive. It was in my capacity as head of government relations and public policy that I oversaw the development of Aventis' position on reimbursement for pharmaceuticals under Medicare and Medicaid.

The pharmaceutical industry has seen many changes since I joined Marion. The complexity, potency and value of the products the industry develops have changed, as has the entire distribution system for those products. One thing, however, has not changed: the reliance on AWP as a reimbursement benchmark by both government and private payers. To understand this reliance, one has to look back nearly 40 years.

In the late 1960's, about the only people who did not pay for prescription drugs out of their own pockets were employees of pharmaceutical companies and people who qualified for Medicaid. Therefore it fell to Medicaid to try to build systems to meet the task. I think it is important to remember that in the 60's, a computer with as much computing power as today's notebooks had not been built and would have filled a large building. Medicaid needed simple manual systems.

As a result, the concept of Average Wholesale Price or AWP was created by the director of Medi-Cal, the California Medicaid Agency. The idea was that rather than having a pharmacist report what he had paid to purchase a product (and then going through some type of audit procedure to verify that he had truly paid such a price) it would be administratively simpler to always pay the same amount for a given drug. At the time it was established, AWP was not intended to be what was actually paid by the pharmacist to the wholesaler, but it was a good surrogate for administrative efficiency. Beginning in 1969, Medi-Cal reimbursed pharmacies for Medicaid patients' prescriptions by paying AWP plus a dispensing fee. As third party coverage of prescription drug costs became

more widespread – both by government and private payers – the reliance on AWP became more pervasive.

Let me fast-forward through two of the major trends in the pharmaceutical industry that have made AWP a problematic reimbursement benchmark. These trends are consolidation in the wholesale drug industry and the rise of managed care including Pharmacy Benefit Managers (PBM's.)

For branded prescription drugs, AWP typically reflects a 20% to 25% mark up over the Wholesale Acquisition Cost (the manufacturer's list price to wholesalers also known as WAC.) This mark up roughly corresponded to the wholesaler's mark up in the early days of AWP. However, drug wholesalers have seen technological change that has dramatically increased the efficiency of scale in that industry. That change fostered incredible competition and led to consolidation of the industry. Three companies now account for over ninety percent of the wholesale drug business and they do it on gross margins of less than five percent. That means that an AWP that remained static at a twenty to twenty-five percent markup over WAC began to overstate the price paid by the retail pharmacist.

The 1980's saw the rise of managed care and PBM's. Whatever else they may have done, they forced big pharmaceutical companies to aggressively compete on price. They did this by limiting the number of drugs that a drug plan would pay for and then negotiating with the manufacturers for rebates to be on the preferred list (known as a

formulary.) They also forced pharmacies to compete on price by requiring pharmacists to sign contracts if they wanted to serve the population covered by the plan. I should point out that all of these agreements used AWP as the benchmark price.

While these trends were occurring, there was tremendous pressure to maintain AWP at a fixed markup from WAC. AWP had been codified as the benchmark price, by statute or regulation in the public sector and by contract in the private sector. As the difference between AWP and the real prices paid by pharmacists and providers began to increase, the difference was used to compensate for lack of payments for services. A change in the current, well-known relationship of AWP to WAC would have far reaching effects on the provision of health care services.

In 1990, Congress recognized that private sector payers were able to negotiate substantial discounts from pharmaceutical manufacturers. To take advantage of these negotiations for Medicaid, Congress included provisions in the Omnibus Budget Reconciliation Act requiring pharmaceutical manufacturers to pay a rebate on Medicaid purchases that was based on the "Best Price" negotiated by private sector payers.

In 2001, the Office of the Inspector General of the Department of Health and Human Services and the General Accounting Office both issued reports that found that Medicare providers were paying substantially less than AWP to obtain the drugs they dispensed to patients and recommended government reimbursements to providers for drugs be brought more in line with acquisition costs. As committee staffs were considering the question,

Aventis met with them to recommend adopting acquisition cost as the amount for reimbursement. This recommendation was formally adopted by Aventis management in 2002.

The 2002 Aventis policy document, which was provided by Aventis to the Committee, reflects the result of an effort to point out the problems associated with relying on AWP benchmarking in government reimbursement of prescription drugs given the realities of the changed environment in which those products are used. It was Aventis' view that an appropriate reimbursement methodology needed to reimburse providers for the drugs they dispensed at or near their cost to acquire those drugs, while also fully and appropriately paying them for the professional services they provided in connection with dispensing those products.

I appreciate the opportunity to appear before the Committee today, and will be happy to answer your questions regarding the use of AWP as a basis for reimbursement.